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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,394	09/17/2003	Kurt-Reiner Geiss	7390-X03-018	4213

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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,394	GEISS, KURT-REINER	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 09/17/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of IDS filed on 09/17/2003 is acknowledged.

Claims 1-13 are pending in this application and claims 1-13 will be prosecuted on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 3 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protecting against attention deficit disorders and lack of concentration and protecting against impaired memory and learning disorders, improving attentiveness and concentration, improving memory and learning ability and/or to use in learning and training process , does not reasonably provide enablement

for **preventing** against attention deficit disorders and lack of concentration and **preventing** against impaired memory and learning disorders, improving attentiveness and concentration, improving memory and learning ability and/or to use in learning and training process.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1).

Nature of the Invention:

The claims are drawn to a method comprising consuming the food of Claim 1 and a bar of claim 5 to prevent against attention deficit disorders and lack of concentration and prevent against impaired memory and learning disorders to improve attentiveness and

concentration, to improve memory and learning ability and/or to use in learning and training processes.

(2).

State of the Prior Art:

The skilled artisan would view that preventing against attention deficit disorders and lack of concentration and preventing against impaired memory and learning disorders, improving attentiveness and concentration, improving memory and learning ability and/or to use in learning and training process is highly unlikely. Prior art by Evans et al. ((US PG Pub. 2002/0048612 A1) depict treating cognitive and emotional disorders but not preventing any of the cognitive disorders.

(3).

Relative Skill of Those in the Art:

The relative skill of those in the art is extremely high.

(4).

Predictability of the Art:

The prevention against attention deficit disorders and lack of concentration and prevention against impaired memory and learning disorders is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5).

Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the prevention against attention deficit disorders and lack of concentration and prevention against impaired memory and learning disorders.

(6).

Direction or Guidance Presented:

The specification does not provide any guidance as to the method of preventing against attention deficit disorders and lack of concentration and preventing against impaired memory and learning disorders.

(7). Working Examples and (8). Quantity of Experimentation Necessary:

The instant term "prevention" denotes that the attention deficit disorders and lack of concentration and impaired memory and learning disorders do not occur again during the lifetime of a subject consuming the claimed food / food bar. A review of the instant specification does not reveal any experimental data to prove that the actual prevention is possible. The quantity of experimentation will be very high. Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidance, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-8 and 10 recite the limitation "preferably" which makes the claim indefinite because it is unclear as to whether the limitation is really the limitation or not. Claims 9 and 11-13 are indefinite for being dependent on indefinite claim. Claims 1, 5 and 7 recites the limitation "cognitive functional capacity". The meets and bounds of the claim are not clear. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al. (US pub no. 2003/0161861 A1) in view of Strumor et al. (US Patent No.

6149939).

Lang et al. discloses a cereal product comprising starch, which improves cognitive performances, in particular memory retention, attention concentration, vigilance and /or mental well being in people and particularly in a child and an adolescent. Table 1 on page 2 discloses a composition comprising spaghetti, kidney beans potatoes white bread and whole meal bread etc. Table 8 depicts carbohydrates, proteins and lipids.

While Lang et al. discloses lipids in their composition, Lang et al. does not disclose phosphatidyl serine specifically. Strumor et al. discloses dissolvable oral tablets and mini bars for aiding memory which contain healthful ingredients such as oxygen enhancers, vitamins, enzymes, dehydrated foods, soy proteins, herbs, roots, vitamins and phosphatidyl serine. (See abstract and examples I-IV).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate phosphatidyl serine in the composition forwarded by Lang et al. because the composition comprising phosphatidyl serine helps in aiding memory. A skilled artisan would thus have been motivated to prepare a functional food comprising phosphatidyl serine, vitamins, proteins and carbohydrates with a reasonable expectation of success. With respect to various amounts and percentages of various components, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time the invention was made by doing experimental manipulations. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1615

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